REMARKS

The Office Action has been received and carefully considered. The Office Action rejects claims 12-19, 21-24 and 59 under 35 U.S.C. § 101 as allegedly being directed to nonstatutory subject matter, and rejects claims 12-24 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants respectfully traverse these rejections. Reconsideration of claims 12-24 and 59 is respectfully requested based on the following remarks.

I.   The Claims Are Directed To Statutory Subject Matter

The Office Action rejects independent claims 12 and 59 as allegedly being directed to non-statutory subject matter. In particular, the Office Action alleges that claims 12 and 59 are not directed to producing a useful, concrete and tangible result. Applicants respectfully traverse these rejections, and with them the rejections of the dependent claims, as explained in detail below.

Applicants preface the remainder of this section by asserting that the requirement of being "useful, concrete, and tangible" is *not relevant* to the pending claims, which are directed to a patentable method of scoring a match between two peptides. The "concrete, useful and tangible" requirement arose in the *State Street* opinion as an analytical tool to separate patentable subject matter from non-statutory *mathematical algorithms*. *See State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 USPQ2d 1596 (Fed. Cir. 1998). *State Street* does not imply that peptide match scoring methods must satisfy the "useful, concrete, and tangible" test; rather, *State Street* mandates this test only for mathematical algorithms. The test is inapplicable to peptide match scoring methods such as those claimed in the present application. Nevertheless, to

ensure a complete record and expedite prosecution, Applicants state that the present claims meet

the *State Street* standard for mathematical algorithms, as discussed immediately below.

A.   The Pending Claims Are Directed To A Useful Invention

The claims are directed to a "useful" invention. As best understood, "useful" in this context

requires some practical utility or real-world value. For the record, Applicants traverse this

alleged requirement of § 101. Specifically, "practical utility" is a requirement of 35 U.S.C.

§ 112, first paragraph, and is improperly shoehorned into an analysis under § 101. Nevertheless,

the pending claims are directed to an invention with great practical utility and real-world value as

discussed presently.

The claims are directed to outputting information based on scoring an extended match. In

particular, the independent claims recite "scoring the extended match" and "outputting

information based at least in part on the step of scoring the extended match." The Office Action

appears to assert that outputting information based on scoring an extended match is not "useful"

as allegedly required under 35 U.S.C. § 101. With respect, this position is untenable.

The Office Action incorrectly understands what is claimed as being outputted. Specifically, the

claims do not recite outputting E. Rather, the claims recite outputting information based on

scoring E. Scoring E, according to the claims, is performed *based on a likelihood ratio* L. The

Office Action incorrectly asserts that "'E' is ... just a theoretical score." Office Action, page 4.

To the contrary, the extended match, E, is *not a score*, theoretical or otherwise. The extended

match *is* a probabilistic function of a tuple of random variables. *See* claims 1 and 59. As

claimed, this tuple is *scored, based on a likelihood ratio* L. *See* claims 1 and 59. The claims are *not* directed to outputting E, rather, the pending claims are directed to outputting information *based at least in part on the step of scoring the extended match, which itself is based on a likelihood ratio.* Such information includes, for example, the value of L itself, or a list of peptides with the best score. *See, e.g.,* Specification, paragraph 165. Accordingly, the claims recite outputting useful information.

Outputting information based on scoring an extended match, as claimed, is unquestionably useful. As is readily appreciated, scoring peptide matches can be technically difficult. Any technique that can assist in improving scoring peptide matches would be highly useful. Thus, the pending claims are plainly directed to a useful invention.

B.   The Pending Claims Are Directed To A Concrete Invention

The Office Action misapplies the alleged requirement of outputting "concrete" information. Specifically, the Office Action asserts that "it is not clear what the result of the claimed steps is intended to be, therefore the result is not concrete." Office Action, page 4. With respect, this analysis is not in conformance with the alleged requirement of being "concrete" under 35 U.S.C. § 101.

The MPEP sets forth the alleged requirements of the "concrete" test. "Usually, this question [of being concrete] arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again." MPEP § 2106(IV)(C)(2)(2)(c). Thus, as best understood, the term "concrete" in

this context means that the claimed invention must produce an assured or reproducible result. Again, the pending claims plainly meet this alleged criterion. The claims are generally directed to scoring a peptide match. There is nothing uncertain about the results recited in the pending claims. The claimed methods are not "unpredictable," as some biological arts may be. Instead, the claims are directed to certain computations, which are typically performed by a computer. Following the method claim steps will assuredly produce the desired result: outputting information based on scoring the extended match. Accordingly, the pending claims are directed to a "concrete" invention.

C.   The Pending Claims Are Directed To A Tangible Invention

Finally, the claims are directed to producing a "tangible" as opposed to "abstract" result. The Office Action appears to acknowledge this. "Said outputting step is tangible." Office Action, page 5. Applicants agree.

There is nothing abstract about the subject matter of the pending claims. As discussed above, following the steps recited in the claims assuredly produces peptide match information. This real-world result improves over prior art techniques for scoring peptide matches. There is nothing abstract about the result produced by the claims. Rather, the end result is entirely tangible: the output of peptide match information.

II.   The Claims Meet The Requirements Of 35 U.S.C. § 112

The Office Action requests clarification regarding the relationships between the *extended match E*, the step of *scoring*, and the *likelihood ratio* L, as claimed. The following summarizes such

relationships by reference to the specification. This discussion is not meant to limit the claims, which are to be interpreted based in their plain language, that which is known to one of ordinary skill in the art and in view of the specification.

Essentially, the ***extended match*** E is part of a mathematical model that contains detailed information concerning and comparing a given experimental peptide and a given candidate peptide. Formally, the extended match E is a tuple of random variables and therefore itself a random variable. *See* Specification, paragraph 78. The precise random variable constituents of E may vary in different embodiments. Nevertheless, the random variables that form E are generally calculated from parameters concerning the given experimental peptide and/or the given candidate peptide. Although E is rife with information concerning the relationship, if any, between an experimental peptide and a candidate peptide, E itself contains such information in raw form. Thus, without further processing and analysis, E, standing alone and uninterpreted, does not readily inform its viewer of the likelihood of a match between the candidate peptide and the experimental peptide, at least not in a user-friendly and easily-readable form. Note that E is *not* a probability. Nor is E a score. Rather, E is a complicated mathematical construction that includes various random variables related to a candidate peptide and an experimental peptide.

In general, ***scoring*** a match between a given candidate peptide and a given experimental peptide involves assigning a quantitative unit to the likelihood that the given experimental peptide is indeed the same as the given candidate peptide. Simply put, scoring a match between an experimental peptide and a candidate peptide involves generating a number that tells how likely it is that the peptides are the same. One type of scoring that is easy to understand is generating a

match probability. That is, one type of scoring includes assigning a probability - *i.e.*, a number between zero and one - that two peptides are the same. The probability value itself is the score. In this example, if the probability that a given experimental peptide is the same as a given candidate peptide is 0.9999, one can be fairly confident that the two peptides are indeed the same. It is important to note that ***probabilities are only one type of scoring***. Other quantitative frameworks exist within which it is possible to assign a numerical value to the likelihood that two peptides match. Claim 20, for example, lists various types of scoring techniques, which include a log-likelihood, a likelihood ratio divided by the length of the experimental peptide measured in amino acids, a log-likelihood divided by the length of the experimental peptide measured in amino acids, and a log-likelihood divided by the logarithm of the length of the experimental peptide measured in amino acids. Each of these scoring frameworks provides different values, analytical features, advantages and disadvantages. However, their commonality is that they each provides a numerical quantity from which it is possible to determine a likelihood that two peptides match.

From the above paragraph, it should be apparent that the ***likelihood ratio*** L is but one type of scoring. In particular, the likelihood ratio may be calculated as a probability that a match exists divided by a probability that a match does not exist. These quantities are typically positive real numbers that range strictly between zero and infinity. (Contrast this type of scoring with scoring using a naked probability of a match, which yields values between zero and one, inclusive.) In short, then, a likelihood ratio is a type of scoring.

Turning now to the rejections under 35 U.S.C. § 112, the above discussion should illuminate the following. The Office Action states that "L ... comprises 'E' scores." Office Action, page 6. Although this may be technically correct, it is misleading. More accurately, it is correct to say that L comprises a ratio of match probabilities, each of which is calculated using E. The Office Action is correct in saying that "'E' is not computed based on the likelihood ratio 'L'". Office Action, page 6. As is apparent from the above discussion, the reverse is true, namely, L is calculated using E. The Office Action again includes a misleading statement in saying that "'L' is computed from the calculations of E." More accurately, L is one type of scoring and is computed in a particular instance in association with a particular E, which itself is constructed relative to two peptides. Thus, Claim 12 is not "backward" as alleged. It recites "*scoring* the extended match *E* based on a likelihood ratio," which involves generating a quantitative value - the likelihood ratio - that acts as a score of the likelihood that the two peptides represented in E are indeed a match. In other words, claim 12 is directed to a particular extended match E, which is formed using parameters relative to the experimental peptide and the candidate peptide recited in that claim, and *scoring* the extended match according to an analytical framework associated with a likelihood ratio as recited in that claim. Accordingly, there is no issue of indefiniteness in claim 12, or claim 59, which includes the same language.

The Office Action improperly implies that the term "based on" renders claims 12 and 59 indefinite. To the contrary, the term "based on" is a widely-used claim limitation. A quick database search reveals that over 350,000 issued U.S. patents - or approximately 5% of all currently-issued U.S. patents - include the term "based on" in their claims. As discussed in Section I(A) above, there are many types of information that may be outputted, including L itself

or a list of the best match candidates. Accordingly, claims 12 and 59 are not indefinite as alleged.

The Office Action further alleges that claims 12 and 59 are indefinite because they recite "probabilities $P(E|D,s,H_1)$ and $P(E|D,s,H_0)$ are calculated based on the stochastic model." To the contrary, this limitation is clear and fully supported by the specification. The Office Action alleges that it is "unclear whether or not the probabilities incorporate information from the stochastic model." Office Action, page 6. To the contrary, the probabilities are recited as being computed based on a stochastic model; accordingly, the probabilities are computed *using* a stochastic model. It does not make sense to inquire whether a probability "incorporates information" from a stochastic model any more than it makes sense to inquire whether a particular document, such as an office action, "incorporates information" from the word processor used to generate it. The claims embrace both possibilities raised in the Office Action. Namely, it is only a matter of semantics as to whether "the model actually calculates the probabilities" versus "further calculations are performed using results from the model which give the probabilities." As the Examiner surely appreciates, stochastic analysis is a complicated field of endeavor. Therefore, it is unfair to demand that the claims recite each and every computation step required in generating a probability value based on a stochastic model, as such a demand would result in a claim the length of a textbook.

The Office Action alleges that it is unclear as to the meaning of the limitation "probabilities ... are calculated." Applicants respectfully disagree. Specifically, Applicants believe that the claim unequivocally recites that the "probabilities $P(E|D,s,H_1)$ and $P(E|D,s,H_0)$ are calculated based on

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the stochastic model." The intended limitation of the probabilities, which are numerical quantities, not "variables" as alleged, is that the probabilities are calculated using a stochastic model. See the discussion in the paragraph above.

The Office Action further alleges, as a basis for rejecting claims 14, 15, 17, 21, 23 and 24, that "it is unclear as to where in the method [of the parent claim] is this step intended to occur and what relationship is intended between this step and the other method steps." Without conceding the truth of these allegations, Applicants respectfully assert that this reasoning is not valid grounds for forming a rejection under 35 U.S.C. § 112. For example, it is well-settled law that method steps may occur in any order that is supported by the specification. *See, e.g., Interactive Gift Express, Inc. v. Compuserve, Inc.* 256 F.3d 1323, 1342 (Fed. Cir. 2001) (holding that a method claim not reciting an order of steps is not construed to require one, unless the method steps implicitly require that they be performed in a particular order); and *Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1322 (Fed. Cir. 1999) ("not every process claim is limited to the performance of its steps in the order written"). Having carefully reviewed the rejections of these claims, Applicants believe that the limitations at issue are fully definite and compliant with 35 U.S.C. § 112, second paragraph, when read by one of ordinary skill in the art in the context of the present specification.

The remaining allegations under 35 U.S.C. § 112, second paragraph are addressed in reference to MPEP § 2173.04. There, the U.S.P.T.O. clearly sets forth its policy on rejections for indefiniteness as follows:

Breadth Is Not Indefiniteness

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.

Undue breadth of the claim may be addressed under different statutory provisions, depending on the reasons for concluding that the claim is too broad. [1] If the claim is too broad because it does not set forth that which applicants regard as their invention as evidenced by statements outside of the application as filed, a rejection under 35 U.S.C. 112, second paragraph, would be appropriate. [2] If the claim is too broad because it is not supported by the original description or by an enabling disclosure, a rejection under 35 U.S.C. 112, first paragraph, would be appropriate. [3] If the claim is too broad because it reads on the prior art, a rejection under either 35 U.S.C. 102 or 103 would be appropriate.

MPEP § 2173.04. Applicants respectfully assert that the Office action appears to be improperly rejecting claims under 35 U.S.C. § 112, second paragraph due to what may be perceived as undue breadth. MPEP § 2173.04 clearly rejects this approach. Turning now to the alternate possibilities recited in that section, Applicants state as follows. First, the Office Action does not allege that the claims are too broad as evidenced by statements outside of the application as filed. Accordingly, a rejection under § 112 would not be appropriate under this rationale. Second, the

claims are fully supported by the specification as filed and are accordingly in compliance with § 112, first paragraph. The Office Action does not allege to the contrary. Third, the claims are not too broad so as to read on prior art. Indeed, the Examiner has withdrawn the prior art rejections issued in the prior office action.

Accordingly, the claims are fully compliant with the requirements set out in Title 35 of the United States code, including Section 112, second paragraph. Applicants respectfully request that the rejections be withdrawn and the case passed to issue.

III.   Conclusion

In view of the foregoing, it is respectfully submitted that the present application is in condition for allowance, and an early indication of the same is courteously solicited. The Examiner is respectfully requested to contact the undersigned by telephone at the below listed telephone number, in order to expedite resolution of any issues and to expedite passage of the present application to issue, if any comments, questions, or suggestions arise in connection with the present application.
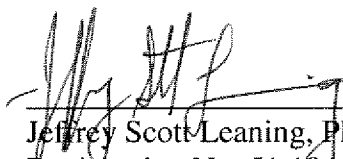
In the event that the U.S. Patent and Trademark Office requires a fees to enter this Reply or to maintain the present application pending, please charge or credit such variance to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

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